

Lesions in Male Mice

C.31

TABLE C4
Summary of the Incidence of Nonneoplastic Lesions in Male Mice in the 2-Year Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Respiratory System			
Larynx	(42)	(41)	(46)
Inflammation, acute	1 (2%)		1 (2%)
Lung	(45)	(47)	(48)
Congestion	3 (7%)	1 (2%)	1 (2%)
Hyperplasia, macrophage	3 (7%)	46 (98%)	48 (100%)
Inflammation, chronic active		16 (34%)	40 (83%)
Thrombosis			1 (2%)
Alveolar epithelium, hyperplasia, focal	1 (2%)		
Peribronchiolar, inflammation, chronic active		1 (2%)	
Perivasicular, inflammation, suppurative	1 (2%)		
Nose	(45)	(46)	(47)
Cytoplasmic alteration, focal	5 (11%)	23 (50%)	40 (85%)
Erosion, focal	1 (2%)	1 (2%)	2 (4%)
Inflammation, acute	4 (9%)	4 (9%)	7 (15%)
Special Senses System			
Ear	(1)		
Inflammation, granulomatous	1 (100%)		
Urinary System			
Kidney	(45)	(46)	(48)
Cast protein	1 (2%)		
Cyst	2 (4%)		
Hydronephrosis	3 (7%)	1 (2%)	
Inflammation, suppurative, focal	3 (7%)	5 (11%)	3 (6%)
Metaplasia, osteous, focal		3 (7%)	
Nephropathy, chronic	3 (7%)		
Capsule, inflammation, suppurative			2 (4%)
Pelvis, inflammation, suppurative	2 (4%)	5 (11%)	1 (2%)
Urinary bladder	(43)	(38)	(43)
Dysplasia, focal	1 (2%)		
Inflammation, chronic active	6 (14%)	5 (13%)	2 (5%)
Ulcer, focal			1 (2%)
Transitional epithelium, hyperplasia		1 (3%)	

* Incidences are expressed as the ratio of animals with lesions to the number of animals examined microscopically at the site.

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**APPENDIX D
SUMMARY LESIONS IN FEMALE MICE
IN THE 2-YEAR INHALATION STUDY
OF TALC**

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Lesions in Female Mice

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TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc^a

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Disposition Summary			
Animals initially in study	50	50	50
Early deaths			
Moribund	2	4	4
Natural deaths	17	21	21
Survivors			
Terminal sacrifice	30	23	25
Missing	1	1	
Culled		1	
Animals examined microscopically	46	48	50
Alimentary System			
Esophagus	(43)	(47)	(48)
Gallbladder	(31)	(28)	(29)
Intestine large, cecum	(35)	(29)	(34)
Leiomyoma			1 (3%)
Intestine large, colon	(38)	(33)	(32)
Leiomyosarcoma		1 (3%)	
Intestine small, ileum	(33)	(27)	(31)
Liver	(46)	(46)	(50)
Hemangioma		1 (2%)	
Hepatocellular carcinoma	7 (15%)	5 (11%)	4 (8%)
Hepatocellular adenoma	5 (11%)	1 (2%)	4 (8%)
Mesentery	(2)		
Pancreas	(42)	(39)	(44)
Salivary glands	(46)	(48)	(50)
Hemangioma	1 (2%)		
Stomach, glandular	(45)	(39)	(46)
Cardiovascular System			
Heart	(46)	(48)	(50)
Alveolar/bronchiolar carcinoma, metastatic, lung		1 (2%)	
Endocrine System			
Adrenal gland	(46)	(45)	(50)
Spindle cell, adenoma	1 (2%)		
Adrenal gland, cortex	(46)	(44)	(50)
Adenoma	1 (2%)		
Adrenal gland, medulla	(41)	(43)	(45)
Pheochromocytoma malignant	1 (2%)		
Pituitary gland	(42)	(42)	(48)
Adenoma	5 (12%)	4 (10%)	2 (4%)
Carcinoma		2 (5%)	
Thyroid gland	(43)	(47)	(49)
Follicular cell, adenoma	1 (2%)	2 (4%)	2 (4%)

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TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³
General Body System			
Tissue NOS	(4)	(1)	(2)
Fibrocarcoma	1 (25%)		
Hemangioma	1 (25%)		1 (50%)
Hemangiosarcoma			1 (50%)
Genital System			
Ovary	(38)	(43)	(46)
Adenocarcinoma, metastatic, uterus	1 (3%)		
Adenoma	1 (3%)	1 (2%)	
Cystadenoma		1 (2%)	
Luteoma	2 (5%)		
Uterus	(44)	(45)	(49)
Adenocarcinoma	1 (2%)		
Carcinoma adenosquamous			1 (2%)
Hematopoietic System			
Bone marrow	(41)	(43)	(45)
Lymph node	(46)	(46)	(49)
Lymph node, bronchial	(38)	(37)	(43)
Adenocarcinoma, metastatic, kidney		1 (3%)	
Adenocarcinoma, metastatic, uterus	1 (3%)		
Alveolar/bronchiolar carcinoma, metastatic, lung		3 (8%)	
Lymph node, mandibular	(35)	(38)	(36)
Lymph node, mediastinal	(13)	(17)	(14)
Adenocarcinoma, metastatic, kidney		1 (6%)	
Alveolar/bronchiolar carcinoma, metastatic, lung		1 (6%)	
Lymph node, mesenteric	(35)	(31)	(37)
Spleen	(45)	(44)	(50)
Hemangiosarcoma			1 (2%)
Thymus	(40)	(40)	(41)
Alveolar/bronchiolar carcinoma, metastatic, lung		2 (5%)	
Integumentary System			
Mammary gland	(41)	(45)	(48)
Fibrosarcoma			1 (2%)
Musculoskeletal System			
Bone	(46)	(48)	(50)
Vertebra, alveolar/bronchiolar carcinoma, metastatic, lung		1 (2%)	
Nervous System			
Spinal cord			(1)
Thoracic, ganglioneuroma			1 (100%)

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Lesions in Female Mice

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TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Respiratory System			
Lung	(46)	(48)	(50)
Adenocarcinoma, metastatic, kidney		1 (2%)	
Alveolar/bronchiolar adenoma	3 (7%)	2 (4%)	2 (4%)
Alveolar/bronchiolar carcinoma	2 (4%)	4 (8%)	1 (2%)
Hemangiosarcoma, metastatic, tissue NOS			1 (2%)
Hepatocellular carcinoma, metastatic, liver	2 (4%)	2 (4%)	
Trachea	(40)	(36)	(45)
Special Senses System			
Harderian gland	(2)	(2)	(1)
Adenocarcinoma			1 (100%)
Adenoma	2 (100%)	1 (50%)	
Urinary System			
Kidney	(46)	(46)	(50)
Adenocarcinoma		1 (2%)	
Hepatocellular carcinoma, metastatic, liver	1 (2%)		
Urinary bladder	(44)	(40)	(41)
Systemic Lesions			
Multiplic organs ^b	(46)	(48)	(50)
Lymphoma malignant histiocytic			1 (2%)
Lymphoma malignant lymphocytic	2 (4%)	3 (6%)	3 (6%)
Lymphoma malignant mixed	3 (7%)	4 (8%)	2 (4%)
Lymphoma malignant undifferentiated cell	2 (4%)		2 (4%)
Tumor Summary			
Total animals with primary neoplasms ^c	31	26	21
Total primary neoplasms	42	33	31
Total animals with benign neoplasms	18	9	10
Total benign neoplasms	23	13	13
Total animals with malignant neoplasms	19	19	15
Total malignant neoplasms	19	20	18
Total animals with metastatic neoplasms	3	5	1
Total metastatic neoplasms	5	13	1

^a Incidences are expressed as the ratio of animals with lesions to the number of animals examined microscopically at the site.^b Number of animals with any tissue examined microscopically^c Primary tumors: all tumors except metastatic tumors

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³

Number of Days on Study	0	4	4	4	5	5	5	5	5	6	6	6	6	6	7	7	7	7	7	7
	3	2	6	8	0	0	0	4	5	9	4	8	8	8	9	2	2	2	2	2
	0	6	5	7	5	6	9	4	2	8	1	0	3	6	2	3	9	9	9	9
Carcass ID Number	5	5	5	3	4	4	3	4	4	4	5	5	4	5	4	4	3	3	3	3
	3	0	3	7	1	2	8	1	7	7	0	2	9	0	4	9	7	8	8	8
	3	0	4	6	7	0	2	5	5	3	5	8	7	7	6	6	7	1	4	6
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Alimentary System																				
Esophagus	+	+	M	+	+	M	M	+	+	+	+	+	+	+	+	+	+	+	+	+
Gallbladder	A	M	A	M	A	M	A	+	A	A	A	A	A	A	A	+	+	+	+	+
Intestine large	A	+	+	A	A	A	+	+	A	+	A	+	+	+	+	+	+	+	+	+
Intestine large, cecum	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Intestine large, colon	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Intestine large, rectum	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Intestine small	A	M	+	M	M	A	A	+	M	A	M	+	+	+	+	+	+	+	+	M
Intestine small, duodenum	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Intestine small, ileum	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Intestine small, jejunum	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hepatocellular carcinoma	X																			X
Hepatocellular adenoma																				X
Mesentery																+				
Pancreas	+	+	A	+	A	A	+	+	+	+	+	I	+	+	+	+	+	+	+	+
Salivary glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemangioma																				
Stomach	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Stomach, forestomach	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Stomach, glandular	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiovascular System																				
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Endocrine System																				
Adrenal gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Spindic cell, adenoma																				
Adrenal gland, cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Adenoma																				
Adrenal gland, medulla	+	+	+	+	+	M	+	M	+	+	I	I	+	+	+	+	+	+	+	+
Pheochromocytoma malignant																				
Islets, pancreatic	+	+	M	+	A	A	M	+	I	M	I	M	I	M	+	+	+	+	+	+
Parathyroid gland	M	M	+	M	+	M	+	M	I	+	M	+	+	+	M	M	M	I	M	+
Pituitary gland	M	+	+	M	M	+	+	+	I	+	+	+	+	+	+	+	+	+	+	+
Adenoma																				
Thyroid gland	A	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Follicular cell, adenoma																				

+: Tissue examined microscopically
A: Autolysis precludes examination

M: Missing tissue
I: Insufficient tissue

X: Lesion present
Blank: Not examined

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Lesions in Female Mice

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³ (continued)

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³ (continued)

Number of Days on Study	0 4 4 4 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7
	3 2 6 8 0 0 0 4 5 9 4 8 8 8 9 2 2 2 2 2 2
	0 6 5 7 5 6 9 4 2 8 1 0 3 6 2 3 9 9 9 9 9
Carcass ID Number	5 5 5 3 4 4 3 4 4 4 5 5 4 5 4 4 3 3 3 3 3 3
	3 0 3 7 1 2 8 1 7 7 0 2 9 0 4 9 7 8 8 8 8
	3 0 4 6 7 0 2 5 5 3 5 8 7 7 6 6 7 1 4 6 9
	1 1
General Body System	
Tissue NOS	+ + + + + + + I + + I M + + + + + + + + + + +
Fibrosarcoma	
Hemangioma	
Genital System	
Ovary	+ +
Adenocarcinoma, metastatic, uterus	
Adenoma	
Luteoma	
Uterus	M I +
Adenocarcinoma	
Hematopoietic System	
Bone marrow	+ + A + A A + A A + + + + + + + + + + + + +
Lymph node	+ +
Lymph node, bronchial	M + + + + M + M M + + + M + + + + + + + + +
Adenocarcinoma, metastatic, uterus	
Lymph node, mandibular	+ + M + + + + + M + + + M + + + + M M +
Lymph node, mediastinal	M M + M M M + M + M M M + M + + M M + M +
Lymph node, mesenteric	M + + M M M + M M + + + I + + + M + +
Spleen	+ + + + + A + + + + + + + + + + + + + + + + +
Thymus	M M + + + M + + + + + + + M + M + + + +
Integumentary System	
Mammary gland	A + + + + A + I + + + M + + + + + + + + + +
Skin	+ +
Musculoskeletal System	
Bone	+ +
Nervous System	
Brain	+ +

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Lesions in Female Mice

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TABLE D2

Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³ (continued)

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TABLE D2

Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³ (continued)

Number of Days on Study	0	4	4	4	5	5	5	5	5	6	6	6	6	6	7	7	7	7	7	7
	3	2	6	8	0	0	0	4	5	9	4	8	8	8	9	2	2	2	2	2
	0	6	5	7	5	6	9	4	2	8	1	0	3	6	2	3	9	9	9	9
Carcass ID Number	5	5	5	3	4	4	3	4	4	4	5	5	4	5	4	4	3	3	3	3
	3	0	3	7	1	2	8	1	7	7	0	2	9	0	4	9	7	8	8	8
	3	0	4	6	7	0	2	5	5	3	5	8	7	7	6	6	7	1	4	6
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Respiratory System																				
Larynx	+	+	+	+	+	A	I	+	+	+	+	+	+	+	+	+	+	+	+	+
Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Alveolar/bronchiolar adenoma																				
Alveolar/bronchiolar carcinoma																				
Hepatocellular carcinoma, metastatic, liver																				
Nose																				
Trachea	A	+	A	+	M	A	A	+	+	+	+	+	+	+	+	+	+	+	+	+
Special Senses System																				
Harderian gland	+																			
Adenoma																				
Urinary System																				
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hepatocellular carcinoma, metastatic, liver																				
Urinary bladder	M	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Systemic Lesions																				
Multiple organs	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymphoma malignant lymphocytic																				
Lymphoma malignant mixed																				
Lymphoma malignant undifferentiated cell type																				

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 0 mg/m³ (continued)

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³

Number of Days on Study	0	0	4	4	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	7	7	7	
	2	9	2	9	0	3	4	5	5	6	1	2	2	4	4	6	7	7	8	9	9	9	0	0	1		
	0	2	2	1	0	4	8	4	9	4	8	1	8	1	5	5	6	8	6	2	9	9	9	2			
Carcass ID Number	1	0	0	1	0	1	1	1	0	1	0	1	0	0	1	1	0	1	1	0	0	1	1	0			
	1	5	1	1	5	4	7	4	1	7	2	2	5	8	3	0	5	7	3	8	6	1	4	2			
	7	5	6	5	0	7	6	8	9	5	2	0	6	1	6	8	8	1	9	3	0	8	0	0			
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
Alimentary System																											
Esophagus	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Gallbladder	A	M	M	M	A	+	+	A	A	A	A	A	A	A	A	M	A	A	+	A	+	A	+	A	+	A	
Intestine large	A	+	A	A	A	+	A	+	A	+	A	+	A	+	A	A	+	A	+	A	+	A	+	A	+	A	
Intestine large, cecum	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Intestine large, colon	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Leiomyosarcoma	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Intestine large, rectum	A	+	A	A	A	M	M	I	M	A	+	M	M	A	A	M	A	+	A	A	A	+	A	+	A	+	
Intestine small	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Intestine small, duodenum	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Intestine small, ileum	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Intestine small, jejunum	A	A	A	A	A	A	+	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
Liver	+	+	+	A	A	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Hemangioma																											
Hepatocellular carcinoma																											
Hepatocellular adenoma																											
Pancreas	+	+	+	A	A	+	+	+	+	+	+	+	+	+	I	M	+	+	A	+	A	+	A	+	I	+	
Salivary glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Stomach	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Stomach, forestomach	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Stomach, glandular	A	+	+	A	A	+	+	+	A	A	+	A	+	A	+	A	+	+	A	+	+	+	A	+	A	+	
Cardiovascular System																											
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Alveolar/bronchiolar carcinoma, metastatic, lung																	X										
Endocrine System																											
Adrenal gland	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Adrenal gland, cortex	+	+	+	A	+	+	+	+	+	+	+	+	M	+	+	A	+	+	+	+	+	+	+	+	+	+	
Adrenal gland, medulla	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Islets, pancreatic	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	
Parathyroid gland	M	I	+	A	A	I	I	+	+	M	I	M	M	M	+	A	+	M	I	M	M	I	I	M	I	I	
Pituitary gland	I	+	+	A	M	M	+	+	M	M	M	+	+	M	+	M	+	M	M	I	+	M	I	+	M	I	
Adenoma	M	+	+	+	+	+	+	+	+	+	+	+	I	+	+	+	M	+	+	M	+	I	+	+	+	+	
Carcinoma																											
Thyroid gland	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	X											
Follicular cell, adenoma																											

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

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TABLE D2

Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

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Lesions in Female Mice

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

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